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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/903,508	07/13/2001	Charles Abbas	1533.0830003/MAC/RGM	3856

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BUCHANAN INGERSOLL PC
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301 GRANT STREET, 20TH FLOOR
PITTSBURGH, PA 15219

EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/903,508

Applicant(s)

ABBAS ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 13-18, 20 and 21 is/are allowed.
- 6) ☒ Claim(s) 5-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed July 12, 2004.

Amendments were made to the claims. Specifically claims 19 and 22-31 were cancelled.

Claims 1-18, 20 and 21 are pending and under consideration in the instant application.

Any rejection of record in the previous Office Action, mailed February 13, 2004, that is not addressed in this action has been withdrawn.

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

The following represents a non-final Office Action on the merits, concerning issues that were not previously raised in the prosecution.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This is a new rejection that is not necessitated by amendment.

It is apparent that specific vectors in claim 5 are required to practice the invention. As such, the vectors must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available,

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the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the vectors.

In the instant case, the process to generate the vectors that is disclosed in the specification does not appear to be repeatable, nor does it appear the vectors are readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

- a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;
- b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;
- c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;
- d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and
- e) the deposit will be replaced if it should ever become inviable.

Applicant is also required to amend the specification to properly indicate the deposit of the biological material in accordance with the rules for deposit of biological materials.

Failure to make one of the preceding indications in response to this Office Action will result in the rejection being maintained in either a second Non-Final or a Final rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 6-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 7 (and their dependent claims) are indefinite for failure to begin with an article. In this instance, it is unclear if the claims are directed only to a plurality of cells, or if the metes and bounds encompass the individual cells within the plurality. **This is a new rejection that is not necessitated by amendment.**

Claim 7 (and its dependent claims) is rejected because it does not begin with a capital letter. As such, it is unclear if there is subject matter encompassed by the claim (i.e., prior to the term "isolated") that is not indicated. **This is a new rejection that is necessitated by amendment.**

Claim 12 is rejected because there are two periods in the claim, thus it is unclear where the claim actually ends. **This is a new rejection that is necessitated by amendment.**

Claim 12 recites the limitation "yeast cells" in reference to claim 7. There is insufficient antecedent basis for this limitation in the claim, because claim 7 does not refer to yeast cells, *per se*. **This is a new rejection that is not necessitated by amendment.**

Claim 12 is rejected under 35 USC 112, second paragraph, as being indefinite for failing to recite a proper Markush group. In order for the claims to be definite, they must recite the proper Markush language, wherein the members of the Markush group are "selected from the

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group consisting of", followed by the listing of the members of the group. In addition, the conjunction "and" must follow the penultimate member of the group. In the instant claim, there are multiple conjunctions, therefore it is unclear what the members of the group. It would be remedial, for example, to indicate that the group consists of "(a) a gene library comprising vectors comprising *Pichia guilliermondii* ATCC 9058 DNA segments, PgARS elements and CfARS elements, and (b) a gene library comprising vectors comprising *Candida famata* VKM Y-9 DNA segments, PgARS elements and CfARS elements," or a variation that more closely indicates the intended groups. **This is a new rejection that is not necessitated by amendment.**

Allowable Subject Matter

Claims 1-4, 13-18, 20 and 21 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636



JAMES KETTER
PRIMARY EXAMINER